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February 7, 2022



VIA ELECTRONIC MAIL

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Re: United States and Tennessee v. Walgreen Co.

E.D. Tenn. No. 2:21-CV-00080

Dear Counsel:

Thank you for conferring with us on February 1, 2022, as required by Rule 30(b)(6) of the Federal Rules of Civil Procedure regarding the matters for examination set forth in Defendant Walgreen Co.'s Notice of Deposition to the Centers for Medicare and Medicaid Services (CMS) issued on January 21, 2022. As explained during our call, the United States objects to Topic Nos. 2, 3, 4, 7, 8, 9, 10, 11, and 12 set forth in Walgreens' deposition notice. Our reasons for those objections are set forth below. Moreover, as stated during our call, the United States tentatively agrees to produce one or more witnesses who can testify about Topic Nos. 1, 5, 6, and 13-26, subject to the parties reaching an agreement on the United States' objections and requests for clarification regarding these topics as set forth below. Although we stated during our February 1 call that we were open to producing a witness who would testify about Topic No. 27 assuming the parties could reach an agreement on the United States' anticipated objections and requests for clarification, upon further review we have determined that this topic is objectionable for the reasons set forth in the United States' objections to Request for Productions Nos. 37-40 in the United States' Responses to Walgreens' Second Requests for Production of Documents.

Rule 30(b)(6) requires that the parties confer about the matters for examination so that the responding party can produce appropriate witnesses who are capable of testifying regarding the noticed topics. However, in order to identify and prepare such witnesses, the topics identified for

examination must be set forth with "reasonable particularity." FED. R. CIV. P. 30(b)(6). Please consider this correspondence as the government's efforts to confer in good faith about the matters for examination set forth in Walgreens' deposition notice.

The United States Objects to Topic Nos. 2, 3, 4, 7, 8, 9, 10, 11, and 12

Each of these topics seek information relating to the government's litigation hold and/or document preservation and collection efforts. Discovery into these areas is objectionable absent a factual basis showing potential spoliation and/or raising questions about a party's preservation or collection efforts. This principle is well-established and is set forth in an authoritative pronouncement from *The Sedona Conference*. As *The Sedona Conference* has stated:

[T]here should be no discovery on discovery, absent an agreement between the parties, or *specific, tangible, evidence-based indicia* (versus *general allegations* of deficiencies or *mere "speculation"*) of a *material failure* by the responding party to meet its obligations. A requesting party has the *burden of proving a specific discovery deficiency in the responding party's production*. See Principle 7 ("The requesting party has the burden on a motion to compel to show that the responding party's steps to preserve and produce relevant electronically stored information were inadequate").

The Sedona Principles, Third Edition: Best Practices, Recommendations & Principles for Addressing Electronic Document Production cmt. 6.b., 19 SEDONA CONF. J. 1, 123-124 (2018) (emphasis added). Thus, in order to seek discovery into the government's document preservation and collection efforts, Walgreens has the burden of proving a specific deficiency in the government's production, and that such deficiency is "material." Additionally, "mere 'speculation'" about the quality of the government's preservation or collection efforts of the type articulated during our February 1 call is insufficient to open the door into the intrusive discovery sought by Walgreens.

The principles articulated by *The Sedona Conference* are also embodied in the case law within this Circuit. *See Edwards v. Scripps Media, Inc.*, 331 F.R.D.116, 125 (E.D. Mich. 2019); *Shufeldt v. Baker, Donelson, Bearman, Caldwell & Berkowitz, P.C.*, Case No. 3:17-cv-01078, 2020 WL 1532323, * 9-12 (M.D. Tenn. March 31, 2020); *Commins v. NES Rental Holdings, Inc.*, Civil Action No. 3:16CV-00608, 2018 WL 3186983, * 9 (W.D. Ky. June 28, 2018); *EPAC Tech., Inc., v. Thomas Nelson, Inc.*, No. 3:12-cv-00463, 2015 WL 13729725, * 6-7 (M.D. Tenn. Dec. 1, 2015) (all stating that discovery about discovery is proper where there is a showing of potential spoliation or issues with a party's preservation/collection efforts). To the extent Walgreens seeks information about CMS' document retention policies, such discovery is improper absent a showing of potential spoliation. *Shufeldt*, 2020 WL 1532323, at * 12.

Notably, *Beaudry v. TeleCheck Serv., Inc.*, 2013 WL 12355782 (M.D. Tenn. March 31, 2013) – the single case cited in Walgreens' January 4, 2022, letter responding to the government's objection to Interrogatory No. 15 in Walgreens' First Set of Interrogatories which

sought information about the government's document hold – is consistent with the above analysis. The court in *Beaudry* allowed discovery into the defendant's retention policies and litigation holds because the plaintiff had evidence of spoliation and a flawed document production. *Id.* at * 2. Because no such evidence exists in this case, *Beaudry* provides additional support for the government's objection to Topic Nos. 2, 3, 4, 7, 8, 9, 10, 11, and 12.

Specifically relevant to this issue is our discussion on February 1 when we asked whether Walgreens contends that relevant information was at one point in existence but no longer exists because it was allegedly lost or destroyed by the United States due to inadequate preservation or collection efforts. Walgreens did not identify any such information in response to the government's question. Absent such evidence, the government objects to Topics Nos. 2, 3, 4, 7, 8, 9, 10, 11, and 12 set forth in Walgreens' deposition notice. If Walgreens believes that relevant information was allegedly lost or destroyed by the United States due to inadequate preservation or collection efforts, please describe such information and the basis for Walgreens' belief that such information was lost or destroyed by the United States due to inadequate preservation or collection efforts.

If you disagree with the United States' objections to these topics, please explain the bases for your disagreement and provide citations to relevant legal authorities that you believe justify discovery into the government's document preservation and collection efforts so that we can evaluate how to best proceed with the Rule 30(b)(6) deposition.

The United States Objects to Topic No. 27

This topic is irrelevant to any party's claim or defense and, accordingly, the request for CMS to produce a 30(b)(6) witness for the topic is not proportional to the needs of the case. See the United States' objections to Request for Productions Nos. 37-40 in the United States' Responses to Walgreens' Second Requests for Production of Documents. Regarding the United States' relevance objection, Walgreens is specifically referred to the description of the Affinity Group provided by the United States in response to Request for Production No. 40. This topic is also per se overbroad to the extent it seeks information "including, but not limited to," the subjects identified therein. See objection to Topic No. 5, infra.

The United States' Tentative Agreement to Produce One or More Witnesses who can Testify about Topic Nos. 1, 5, 6, and 13-26

Rule 30(b)(6) requires that the noticing party "describe with reasonable particularity the matters for examination." Factors that courts consider in determining whether a Rule 30(b)(6) notice satisfies the "reasonable particularity" requirement include: "(1) the nature of the topics; (2) whether the descriptions of the topics include examples of questions and clarifying information such as references to specific named policies, documents, incidents, and the like; and (3) whether a reasonable person reading the notice would understand how to prepare for the deposition." Winfield v. City of New York, No. 15-cv-05236, 2018 WL 840085, * 6 (S.D.N.Y.

Feb. 12, 2018). "Reasonable particularity' requires the topics listed to be specific as to subject area and to have discernable boundaries." *Id.* at * 5.

Before agreeing to produce witnesses on each of the following topics, we request that Walgreens provide the clarifying information requested below, including: examples of the specific types of information requested; clarifying information such as references to specific policies or documents; and/or a list of sample questions you intend to ask the witnesses so they can be prepared to provide responsive information. In addition, where objections are made to the topics below, please narrow the topics in the manner requested and/or explain why you believe such objections are unwarranted.

- No. 1: Please describe and/or identify: the custodians/relevant witnesses from whom you seek responsive information; the specific organizational sections/divisions within CMS to which you are referring; examples of the specific "databases, systems, and servers" to which you are referring (*i.e.*, are you seeking information about emails, folder structure, shared drives, etc.); and whether you are referring only to electronic documents, paper documents, or both. A list of sample questions that you intend to ask relating to this topic would greatly assist the government in identifying and preparing an appropriate witness.
- No. 5: Please describe: the specific investigation to which you are referring (*i.e.*, the criminal investigation, the civil investigation, DOJ's investigation, the State's investigation, etc.); the "information" to which you are referring, including the specific issues you are interested in; and whether there are specific persons from whom you would like responsive information. A list of sample questions that you intend to ask relating to this topic would greatly assist the government in identifying and preparing an appropriate witness. Notably, this topic is *per se* overbroad to the extent it seeks information "including, but not limited to," the subjects identified therein. *Peck v. Cty. of Orange*, Case No. 2:19-cv-04654-DSF-AFMx, 2020 WL 3026377, * 2 (C.D. Cal. May 11, 2020); *Winfield*, 2018 WL 840085, at * 5; *Richardson v. Rock City Mech. Co., LLC.*, No. 3-09-0092, 2010 WL 711830, * 6, 10 (M.D. Tenn. Feb. 24, 2010). Please correct this deficiency.
- <u>No. 6</u>: Please describe the specific types of "information" for which you seek responsive information, including identifying any specific allegations made by the government and/or defenses raised by Walgreens in which you may be interested.
- No. 13: This topic potentially seeks information protected by the deliberative process privilege to the extent it seeks information about "any consideration or review by CMS of such a project or such an application thereof." During our February 1 call, Walgreens indicated it would not seek information protected by the

deliberative process privilege. Please describe why you believe this topic seeks information outside of the privilege. In addition, please describe with more specificity what information you seek relating to "federal financial participation in Medicaid." Moreover, this topic is overbroad and unduly burdensome to the extent it seeks information from CMS about the authority of other component agencies of HHS to grant special demonstration projects.

- No. 14: Please refer to the requests for clarification relating to Topic 13 above. Regarding your request for the "locations of all documents referenced in Topic No. 13 above," please specify whether you are seeking information about the location of paper documents, electronic documents, or both, as well as the specific type of "location" information you are seeking.
- No. 15: The Complaint alleges that the false or fraudulent claims were submitted and paid between October 2014 through December 2016. Accordingly, please limit this topic to the relevant time frame. In addition, please describe the type of information you are seeking, including by providing examples of such information. Also, please describe differences (if any) in the meaning of the following terms used in this topic: "the nature, structure, administration, and oversight."
- No. 16: The Complaint alleges that the false or fraudulent claims were submitted and paid between October 2014 through December 2016. Accordingly, please limit this topic to the relevant time frame. In addition, this topic potentially seeks information protected by the deliberative process privilege to the extent it seeks information about "the development, review, [and] approval" of agency regulations, policies, and guidance. During our February 1 call, Walgreens indicated it would not seek information protected by the deliberative process privilege. Please describe why you believe this topic seeks information outside of the privilege. Also describe the relevance of information relating to "coverage for any Hepatitis C Medication" other than the medications at issue in this case. Furthermore, this topic is overbroad and unduly burdensome to the extent it seeks information from CMS about actions taken by other component agencies of HHS relating to the subjects identified.
- No. 17: The Complaint alleges that the false or fraudulent claims were submitted and paid between October 2014 through December 2016. Accordingly, please limit this topic to the relevant time frame. In addition, this topic is *per se* overbroad to the extent it seeks information "including, but not limited to," the subjects identified therein. *See objection to Topic No. 5, supra*. Please correct this deficiency. Moreover, please describe differences (if any) in the meaning of the following

terms as used in this topic: "development" and "drafting;" and "promulgation" and "implementation." Furthermore, this topic potentially seeks information protected by the deliberative process privilege to the extent it seeks information about "any review, analysis, consideration, or determination relating to whether and to what extent state Medicaid programs have abided by Release No. 172." During our February 1 call, Walgreens indicated it would not seek information protected by the deliberative process privilege. Please describe why you believe this topic seeks information outside of the privilege. Also describe the relevance of information for "any Other DAA" besides the DAAs at issue in this case. Moreover, this topic is overbroad and unduly burdensome to the extent it seeks information from CMS about communications within other component agencies of HHS related to the subject matter of Release No. 172.

- No. 18: The Complaint alleges that the false or fraudulent claims were submitted and paid between October 2014 through December 2016. Accordingly, please limit this topic to the relevant time frame. In addition, this topic potentially seeks information protected by the deliberative process and/or the attorney-client privileges to the extent it seeks information about "reviews, analyses, or evaluations" that may have been conducted into the subjects set forth in this topic, including whether criteria for coverage of Hepatitis C Medication was "consistent with the Social Security Act" or the Medicaid program. During our February 1 call, Walgreens indicated it would not seek information protected by the deliberative process privilege, and I assume the same is true with respect to the attorney-client privilege. Please describe why you believe this topic seeks information outside of those privileges. Furthermore, this topic is per se overbroad to the extent it seeks information "including, but not limited to," the subjects identified therein. See objection to Topic No. 5, supra. Please correct this deficiency. Moreover, please explain the relevance (if any) of information responsive to this request for state Medicaid programs other than TennCare.
- No. 19: The Complaint alleges that the false or fraudulent claims were submitted and paid between October 2014 through December 2016. Accordingly, please limit this topic to the relevant time frame. In addition, this topic is *per se* overbroad to the extent it seeks information "including, but not limited to," the subjects identified therein. *See objection to Topic No. 5, supra.* Please correct this deficiency. Furthermore, this topic potentially seeks information protected by the deliberative process privilege to the extent it seeks information about "CMS's consideration, analysis, or review of the extent to which, and the reasons for which, the Four DAAs... 'have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome' over other Hepatitis C Medications."

During our February 1 call, Walgreens indicated it would not seek information protected by the deliberative process privilege. Please describe why you believe this topic seeks information outside of the privilege. Also describe the relevance (if any) of seeking information about Hepatitis C medications other than the four DAAs at issue.

- No. 20: The Complaint alleges that the false or fraudulent claims were submitted and paid between October 2014 through December 2016. Accordingly, please limit this topic to the relevant time frame. In addition, this topic potentially seeks information protected by the deliberative process privilege to the extent it seeks information about CMS's role "in the development, review, implementation, and/or post-implementation of TennCare's prior authorization criteria. . . ." During our February 1 call, Walgreens indicated it would not seek information protected by the deliberative process privilege. Please describe why you believe this topic seeks information outside of the privilege. Also describe the relevant (if any) of seeking information about "any other Hepatitis C Medication" other than the four DAAs at issue.
- <u>No. 21</u>: The Complaint alleges that the false or fraudulent claims were submitted and paid between October 2014 through December 2016. Accordingly, please limit this topic to the relevant time frame.
- No. 22: The Complaint alleges that the false or fraudulent claims were submitted and paid between October 2014 through December 2016. Accordingly, please limit this topic to the relevant time frame. In addition, this topic is *per se* overbroad to the extent it seeks information "including, but not limited to," the subjects identified therein. *See objection to Topic No. 5, supra*. Please correct this deficiency. Furthermore, this topic potentially seeks information protected by the deliberative process privilege to the extent it seeks information about CMS's "involvement in the development, review, approval, and implementation of the Preferred Drug List and/or of TennCare's prior authorization criteria for any Hepatitis C Medications." During our February 1 call, Walgreens indicated it would not seek information protected by the deliberative process privilege. Please describe why you believe this topic seeks information outside of the privilege. Also describe the relevance (if any) of seeking information about Hepatitis C Medications other than the four DAAs at issue.
- No. 23: The Complaint alleges that the false or fraudulent claims were submitted and paid between October 2014 through December 2016. Accordingly, please limit this topic to the relevant time frame. In addition, this topic is *per se* overbroad to

the extent it seeks information "including, but not limited to," the subjects identified therein. *See objection to Topic No. 5, supra*. Please correct this deficiency. Furthermore, this topic is overbroad and unduly burdensome to the extent it seeks information from CMS about any approvals that other component agencies of HHS must provide for special demonstration projects.

- No. 24: The Complaint alleges that the false or fraudulent claims were submitted and paid between October 2014 through December 2016. Accordingly, please limit this topic to the relevant time frame. In addition, this topic is *per se* overbroad to the extent it seeks information "including, but not limited to," the subjects identified therein. *See objection to Topic No. 5, supra.* Please correct this deficiency. Also, please describe the meaning of "budgetary implications of the waiver," and specifically the type of information you seek regarding same. Furthermore, this topic potentially seeks information protected by the deliberative process privilege to the extent it seeks information about "any review, analysis, consideration, or determination by CMS" related to whether TennCare's prior authorization criteria were permissible under the waiver. During our February 1 call, Walgreens indicated it would not seek information protected by the deliberative process privilege. Please describe why you believe this topic seeks information outside of the privilege
- No. 25: The Complaint alleges that the false or fraudulent claims were submitted and paid between October 2014 through December 2016. Accordingly, please limit this topic to the relevant time frame. In addition, this topic is *per se* overbroad to the extent it seeks information "including, but not limited to," the subjects identified therein. *See objection to Topic No. 5, supra*. Please correct this deficiency. Finally, we need further clarification about the kind of information you seek through testimony related to this topic. After consultation with our client, it is our understanding that CMS does not perform utilization management functions for Medicaid covered outpatient drugs; rather that function is performed by states and their agents.
- <u>No. 26</u>: This topic is overbroad and unduly burdensome to the extent it seeks information from CMS for actions taken by other component agencies of HHS.

Potential Dates for the Depositions Requested by Walgreens

Assuming that we are able to reach agreement on the objections and requests for clarification with respect to Topic Nos. 1, 5, 6 and 13-26 with sufficient time to adequately prepare the designated witnesses, CMS anticipates being able to offer witnesses as follows. In order to adequately prepare witnesses on these topics, we will need to reach an agreement on the

clarifying and other information requested by the United States at least two weeks prior to the depositions.

Topics	Anticipated Witness	Anticipated Availability
1, 5, 6, 13 and 14	Representative from CMS Office of Strategic Operations and Regulatory Affairs, Issuance, Records & Information Systems Group	March 2022 dates generally available with the exception of March 2-4; Mar. 7 (PM); Mar. 18; Mar. 25
15, 23 and 24	Representative from CMCS State Demonstrations Group, Division of Eligibility and Coverage Demonstrations	Request March 7, 14 or 21; Tuesdays through Thursdays also possible with exception of March 1-3, 23-24
16-22	Representative from CMCS Disabled & Elderly Health Programs Group, Div. of Pharmacy	Dates in March generally available with the exception of March 2-4 and March 25
25-26	To be determined, if necessary (see requests for clarification)	

Please note that we anticipate the representative for topics 16-22 will likely be John Coster, whom you have also noticed for deposition as a fact witness. We propose that his deposition as a fact witness take place following his testimony as a 30(b)(6) witness.

Additionally, you have noticed the deposition of Alissa Mooney DeBoy, and we have offered February 28, March 11 and March 18 as potential dates for her deposition. Please let us know if any of those dates are acceptable.

Very truly yours,

FRANCIS M. HAMILTON III United States Attorney

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Robert C. McConkey, III

Assistant United States Attorney

RCM

cc:

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